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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,740	06/23/2000	Markus Pompejus	BGI-121CP	4954

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/606,740	POMPEJUS ET AL.	
	Examiner	Art Unit	
	Christian L Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7,10-16 and 40-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,10-16 and 40-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1, 4-7, 10-16, and 40-44 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1, 4-7, 10-16, and 40-44 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants' arguments filed 10/20/2003 have been fully considered but they are not persuasive. Applicants' position is that the specification teaches homology sequence analysis showing that the claimed invention has structural homology to diaminopimelate epimerase proteins. The Examiner disagrees for reasons of record as supplemented below.

The specification discloses the nucleotide sequence of SEQ ID NO: 1 and the deduced amino acid sequence of SEQ ID NO: 2 and assigns the protein encoded as a diaminopimelate epimerase (Table 1). The specification does not show any enzyme assays to demonstrate that the encoded protein has a diaminopimelate epimerase activity. SEQ ID NO: 2 is referred to by the specification in Table 1 as having the identification code of RXA02229. In Table 4 (p. 23 specification) SEQ ID NO: 2 has only 40-53% identity to mycobacterium tuberculosis nucleotide sequences which are not assigned a function.

Homology is not a disclosure of how to use the protein or polynucleotide encoding the protein of SEQ ID NO: 2. The specification does not state that homology to a reference polypeptide in the prior art is a disclosure that the claimed invention has the properties or biological function of the reference polypeptide relied upon.

One of skill in the art cannot conclude that the invention is a diaminopimelate epimerase since Attwood et al. and Ponting (references attached to the previous Office Action) teach that protein structure and function cannot be predicted based on only its sequence or structure.

Substantial utility is one that provides a specific benefit in currently available form at the time of filing of the invention. However, the main utility of the nucleic acid and protein is to carry out further research to identify the biological function and possible diseases associated with the protein. Utilities that require or constitute carrying out further research to identify or reasonably confirm a specific use are not substantial utility and do not provide a specific benefit. Thus, the claimed invention has no specific or substantial asserted utility.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 4-7, 10-16, and 40-44 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 1, 4-7, 10-16, and 40-44 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore claims 6, 42, and 43 which encompasses any nucleic acid molecule comprising a nucleotide sequence which has at least 90% identity to SEQ ID NO: 1 or complement thereof is not enabled by the specification.

Applicants' arguments filed 10/20/2003 have been fully considered but they are not persuasive. Applicants' position is that the specification teaches assays for identifying the claimed invention and that only routine experimentation is required. The Examiner disagrees for reasons of record as supplemented below.

Teaching regarding how to screen for and identify the claimed invention is not teaching regarding how to make the claimed invention. Knowledge regarding the nucleotides to change, i.e. delete, insert, substitute, and combinations thereof, to make a nucleic acid molecule having at least 90% identity to SEQ ID NO: 1 is lacking. Furthermore, knowledge regarding the biological function of any nucleic acid molecule having at least 90% identity to SEQ ID NO: 1 is lacking.

Thus, searching for specific nucleotides to change to make the claimed nucleic acid is well outside the realm of routine experimentation and predictability in the art of success is extremely low. Such experimentation entails selecting specific nucleotides to change, i.e. delete, insert, substitute, and combinations thereof, to make a nucleic acid molecule having at least 90% identity to SEQ ID NO: 1 and determining the biological function and utility of the nucleic acid. Also well outside the realm of experimentation is identifying the function and use of the nucleic acid molecule having at least 90% identity to SEQ ID NO: 1.

Since routine experimentation in the art does not include such enormous experimentation, where the expectation of determining the biological function of a nucleic acid molecule having at least 90% identity to SEQ ID NO: 1 is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific nucleotides to change and the biological function and utility of the nucleic acid molecule. Without such a guidance, the experimentation left to those skilled in the art is undue.

6. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have not provided arguments to address this rejection.

Claim 7 is directed to all possible polynucleotides having at least 22 contiguous nucleotides of SEQ ID NO: 1. The specification, however, only provides a single representative species encompassed by these claims: a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 1. The specification does not provide a written description of the 5' and 3' nucleotide sequence of the claimed 22 contiguous nucleotides of SEQ ID NO: 1 nor has the specification provided a written description of the entire genus of polynucleotides as encompassed by the claim. There is no disclosure of any particular structure to function/activity relationship in the claimed 22 contiguous nucleotides of SEQ ID NO: 1.

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 5, 6, 15, 16, and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 6 are vague and indefinite because it is not known whether or not the phrase "is capable of functioning" limits the polypeptide to having diaminopimelate epimerase activity. Amending the claim to recite that the polypeptide "has diaminopimelate epimerase activity" may overcome this rejection.

Claims 15 and 16 are vague and indefinite because the meaning of the phrase "modulation in production of a fine chemical" is not known and the specific identity of the fine chemical is not known and not recited in claims 15 and 16. Applicants' arguments have been considered but are not persuasive since Applicants have not specifically recited the specific identify to the "fine chemical" in the claim nor has the specification taught when a compound or

element is or is not a "fine chemical".

Claim 43 is vague and indefinite because the specific identity of the polypeptide which is "capable of modulating production of a fine chemical" is not known and not recited and because of the phrase "fine chemical" for the reasons stated above.

Claim Rejections - 35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Smith (Accession U00019).

Smith (Accession U00019) teach a nucleic acid molecule which is expected to hybridize to the nucleic acid of SEQ ID NO: 1 since the claim does not recite a stringent hybridization condition of 02.X SSC, 0.1% SDS at 65°C (see alignment attached in the previous Office Action).

Conclusion

11. No claim is allowed.

12. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

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